REMARKS

Reconsideration of the present application is respectfully requested. In a First Office action, claims 1 and 3-8 and 32 were said to be anticipated by Schlapfer (U.S. No. 5,501,684), while claim 31 was said to be rendered obvious by this reference. In tendering the anticipation rejection of independent claim 1, it was asserted that Schlapfer shows a compressible flexible element that is configured to expand along the longitudinal axis of the stabilization element, as well as an adjustment element configured to compress the flexible element to adjust its flexibility. The element 2e of Schlapfer was said to be compressible because when its collet construction is expanded it is pressed against the inner walls of the borehole 31 to lock the components together. The element was further said to expand along the longitudinal axis because its collet construction causes it to expand in all directions, which would necessarily include the direction of the axis. Finally, the nut 6 was regarded as configured to compress the element 2 and thereby adjust its flexibility. The expansion of the collet structure of the member 2 and the resulting "compression" against the inner walls of the borehole was considered to correspond to adjusting the flexibility of the element. This rejection was repeated in the present Final Office Action.

In response to the First Office Action, Applicants amended claim 1 to recite that compression of the flexible element adjusts the amount of relative pivoting. Applicants also pointed out that the rejection of claim 1 relies upon an incorrect definition of the terms "compressible" and "compress", and that the collet-type member 2 in Schlapfer moves in exactly manner that is opposite to "compression" – namely, that it expands in all directions as a result of the slits 24, as admitted in the Office Action. The entire function of the Schlapfer device relies upon the expansion of the member 2 into contact with the bore 31, and not compression of the element. Applicants further explained that it is well-known that collet-type devices rely upon frictional contact between the expanding surface and the contact surface and that tightening the collet increases the normal force between the two surfaces, which increases the friction force that must be overcome to permit relative movement. Tightening the nut 6 in

Schlapfer and conical head section 11 simply increases the normal force, which increases the friction force between the two surfaces. The primary object of the clamping element 2 in Schlapfer is to clamp, meaning that there is no movement between the screw 1 and the connecting piece 3. If the forces associated with tightening the nut 6 are absorbed by compressing the clamping element 2, then its clamping function is disrupted.

In response to these arguments, it was theorized that the element 2 of Schlapfer "is clearly compressed against the inner walls of the borehole". The element 2 was "considered flexible" because it expands at the slits in the collet structure. The Office Action concluded that "the adjustment member denoted by ref. #6 appears configured to compress the flexible element to thereby adjust the flexibility of the flexible element because the adjustment member forces the element to expand and therefore compress against the inner walls of borehole ref/ #31. Because the element becomes increasingly tightened until it is locked in the borehole due to its slit expansion and resulting compression against he inner walls of the borehole, the adjustment nut can be considered to adjust the flexibility of the flexible element to adjust the amount of relative pivoting as it produces this tightening/locking action." [Emphasis added]. In essence, this highlighted language from the Office Action reveals that the anticipation rejection is based only upon conjecture. There is no legitimate dispute that the collet of Schlapfer works as Applicants explained – by increasing the frictional force between the expandable collet 2 and the inner walls of the borehole 31.

Beyond relying upon conjecture, the anticipation rejection is based on a faulty analysis of the manner in which the Schlapfer device operates. Claim 1 defines the flexible element as "being configured to expand along said longitudinal axis as said element is compressed". However, the collet 2 expands before it is compressed. Using the terminology from the Office Action, the collet cannot "compress" until it is in contact with the walls of the borehole, and this cannot occur until the collet has expanded sufficiently from its original condition. Moreover, as relied upon in the Office Action, it is this expansion of the collet 2 that leads to the alleged "compression". The expansion of the collet is not

produced by any compression of the collet, as is required by claim 1. Any actual compression of the Schlapfer collet 2 must necessarily work against expansion. In fact, the definition of "compression" applied in this Office Action depends on this resistance to expansion. If the walls of the borehole do not resist or push against expansion of the collet then there can be no "compression" of the collet between the conical head section 11 and the borehole 31. In other words, the very basis behind the definition of "compression" used in the Office Action to reject Applicants' claims is exactly contrary to the actual language of these claims.

Claim 1 further defines the adjustment element as being configured to compress the flexible element to thereby adjust the flexibility of the flexible element. According to the Office Action, the collet element 2 of Schlapfer is "considered flexible" because the element expands "as a result of its slits". There is absolutely nothing presented in the Office Action that establishes that the action of the slits changes at all as the collet element 2 expands and "compresses". As is known in collet design, the slits 24 act as mechanical hinges, while the full height slit 27 allows the collet to expand circumferentially. There is nothing in Schlapfer or in the Office Action to explain how the hinge action of the slits 24 of the expansion clearance provided by the full height slit 27 is altered or adjusted in any manner whatsoever. The allegation that the nut 6 of Schlapfer somehow adjusts the flexibility of the element 2 is clearly incorrect and unsupported by anything in the reference or in the Office Action itself. This erroneous conclusion was based simply on the role of the nut 6 in forcing the collet 2 to expand and therefore "compress" against the borehole. Even in this attempted explanation, there is no discussion of the structure of the collet that was identified as providing the requisite "flexibility", namely the slits of the collet.

Finally, it was surmised that the Schlapfer collet and nut provided means to adjust the amount of relative pivoting. Notwithstanding the clear errors that preceded this conclusion, even this statement of the operation of the Schlapfer device is in error. First, Schlapfer does not contemplate any relative pivoting between the stabilization element and the bone anchor – it is a "fixation device"

that is intended to "quickly be locked in rigid fashion". Col. 2, ll. 1-5. The Schlapfer device is intended to address a disadvantage of the prior art that "the bone screw is not rigidly attached to the bone plate." Col. 1, ll. 33-35. Thus, Schlapfer specifically teaches away from any relative pivoting, and certainly teaches away from any adjustment to the amount of relative pivoting.

As best understood, the argument presented in the Office Action is that as the collet element 2 is gradually tightened or locked the amount of relative pivoting is adjusted. However, this tightening of the collet element of Schlapfer does not adjust the amount of relative pivoting. At best, tightening the collet increases the frictional force, which thus increases the amount of force required to pivot the fixation element 1 relative to the connecting element 3. That is how a collet works. In the absence of any physical stop, the amount of rotation of the collet within the borehole is not changed. As should be apparent from FIG. 1 of Schlapfer the only constraint on the amount of relative pivoting is the point at which either the conical head section 11 or the nut 6 contacts the body of the connecting element 3.

Ultimately, the collet system in the Schlapfer device operates according to known mechanical principles. The function of the Schlapfer device is to lock the assembly together "in rigid fashion". In contrast, the invention defined in Applicants' claims provides a dynamic stabilization system which not only permits relative pivoting between the fastener and the connector, but also permits adjustment of the amount of relative pivoting by adjusting the flexibility (not compression) of the element. Even if the Schlapfer device operated in the manner proposed in the Office Action, there is still nothing in Schlapfer that provides adjustment of the amount of relative pivoting.

The very foundation of the arguments presented in the Office Action is flawed and clearly erroneous. Since Schlapfer does not disclose every limitation of Applicants claim 1 it cannot anticipate this claim, or any of its dependent claims.

With respect to claim 4, Applicants explanation was dismissed out of hand because the claim did not specify that "the bearing race is non-integral with the bearing member." This statement in the Office Action is based on a faulty understanding of the construction of bearing systems, including a bearing race. The present application has not applied any different meaning to the term 'bearing race", which, by definition, is separate from the bearing member. It was therefore improper to completely disregard the language of claim 4 and Applicants' arguments in support of the patentability of claim 4 over Schlapfer.

With respect to claim 32, it was suggested, without support, that the collet element 2 of Schlapfer is clearly compressible along an axis substantially perpendicular to the longitudinal axis. As defined in claim 1, the "longitudinal axis" is along the length of the stabilization element. The "perpendicular axis" is thus generally along the length of the bone engaging fastener, as shown in FIG. 2 of the present application. The Final Office Action included a lengthy explanation of the "compression" of the collet element 2 of Schlapfer. According to this explanation, the "compression" is necessarily along the longitudinal axis – i.e., the axis within the connector element 3. The perpendicular axis in Schlapfer is along the fixation element 1. Thus, while the purported adjustment element or nut 6 operates along the perpendicular axis, as required by claim 32, the purported flexible element or collet element 2 is compressed along the longitudinal axis, contrary to claim 32. Thus, Schlapfer fails to disclose every element of claim 32 and therefore cannot anticipate this claim.

Applicants request reconsideration of the rejections of claims 1-8, 31and 32. The anticipation rejections in view of the Schlapfer reference are clearly erroneous and should be withdrawn.

Respectfully submitted,

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